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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/008,296 | 11/13/2001 | Gholam A. Peyman | PMAN-17 | 2702 |

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WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

| EXAMINER | |
|---|---|
| FARAH, AHMED M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3739 | |

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/008,296 | PEYMAN, GHOLAM A. | |
| | Examiner | Art Unit | |
| | Ahmed M Farah | 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *17-24,26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *03/27/2002* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 4, 6, 7, 9, 11, 12, 14, 15, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. U.S. Patent No. 5,633,275.

As to claims 1, 3, 9, 11 and 25, Mori et al. (hereafter US Pat. '275) disclose phototherapeutic methods for treating or alleviating macular degeneration characterized by fluid leakage from neovascularization /new blood vessel proliferation in the macula of a patient, the methods comprising the steps of: providing an effective amount of a photosensitive agent to the blood vessel; activating the blood vessel with a low energy light to damage the vessel; and directing to the macula a high energy light sufficient to generate heat to coagulate the fluid leakage as presently claimed (see column 7, line 46 to column 8, line 2).

As to claims 4 and 12, US Pat. '275 teaches the use of Npe6 as the photosensitive agent (see column 4, line 53).

As to claims 6 and 14, US Pat. '275 uses an argon laser to provide the treatment energy (see column 7, line 65).

As to claims 7 and 15, US Pat. '275 teaches that the spot sizes is in the range of about 500 um as presently claimed (see column 7, line 59).

3. Claims 1, 4, 9, 12, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Guyer U.S. 2003/0171320 A1.

Guyer discloses phototherapeutic methods for treating or alleviating macular degeneration characterized by fluid leakage from new blood vessel proliferation in the macula of a patient, the methods comprising the steps of: providing an effective amount of a photosensitive agent to the blood vessel; activating the blood vessel with a low energy light to damage the vessel; and directing to the macula a high energy light sufficient to generate heat to coagulate the fluid leakage as presently claimed. See claims 1-3 of Guyer.

As to claims 4 and 12, Guyer teaches the use of protoporphyrin as the photosensitive agent. see claim 23 of Guyer.

**Claim Rejections - 35 USC § 103**

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al.

Mori et al, described above, do not particularly teach that the low energy light is applied before the high-energy light. However, the applicant's written description fails to teach that the order of irradiation (application of low/high energy light) is reversed to perform different treatment or to induce specific treatment results. Furthermore, claims 2 and 3 of the instant application clearly teach that the order of irradiation is not critical to the invention.

Therefore, the examiner's position is that since the order of irradiation is not used to perform a specific task, i.e., not critical to the invention, applying the low energy light prior to the high energy light would have been obvious to one skilled in the art at the time of the applicants' invention in order to treat, prevent, or alleviate age-related macular degeneration as presently claimed.

6. Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. in view of Exhibit A "The latest research on photodynamic therapy for macular degeneration," American Federation for Aging Research, April 3, 2003, www.infoaging.org/d-macu-6-r-photodynamic.html.

Although Mori et al teach the use of various types of photosensitive agents, and a laser source capable to provide power and radiation intensity to activate the photosensitive agent as presently claimed (see column 6, lines 43-46), they do not particularly teach the use of verteporfin.

However, exhibit A clearly teaches that the use of verteporfin as a photosensitizing agent during treatment of age-related macular degeneration (AMD) has been known in the art for more than a decade. Thus, it would have been obvious to one skilled in the art at the time of the applicants' invention to use verteporfin as an equivalent alternative photosensitizing agent during photodynamic treatment of AMD.

7. Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. in view of the publication by the Choroidal Neovascularization Prevention Trail Group "Laser Treatment in Eyes with Large Drusen: Short-term Effects Seen in a Pilot randomized Clinical Trial," Arch. Ophthalmol., February, 2001; 119: 198-207.

Mori et al., described above, do not the number of laser shots/spots as recited in the claims. However, the publication by the Choroidal Neovascularization Prevention Trail Group clearly teaches that the number of laser shots/spots varies depending on the desired results. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Mori et al. in view of the publication by the Choroidal Neovascularization Prevention Trail Group, and increase the treatment shots/spots in order to provide the desired results.

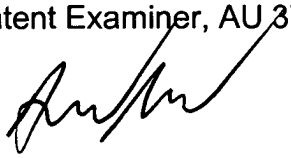
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (703) 305-5787. The examiner can normally be reached on Mon-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0758.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-3590.

A. Farah
Patent Examiner, AU 3739



06/10/2004